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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,853

11/20/2003

Eric John Gandras

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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

10/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,853	<b>Applicant(s)</b> GANDRAS, ERIC JOHN	
	<b>Examiner</b> Phillip Gray	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/20/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This Office action is in response to applicant's communication of 7/28/2009. Currently amended claims 1-31, and 33-38 are pending and stand rejected. Claims 32, and 39-64 were cancelled previously by applicant.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-31 and 33-38 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

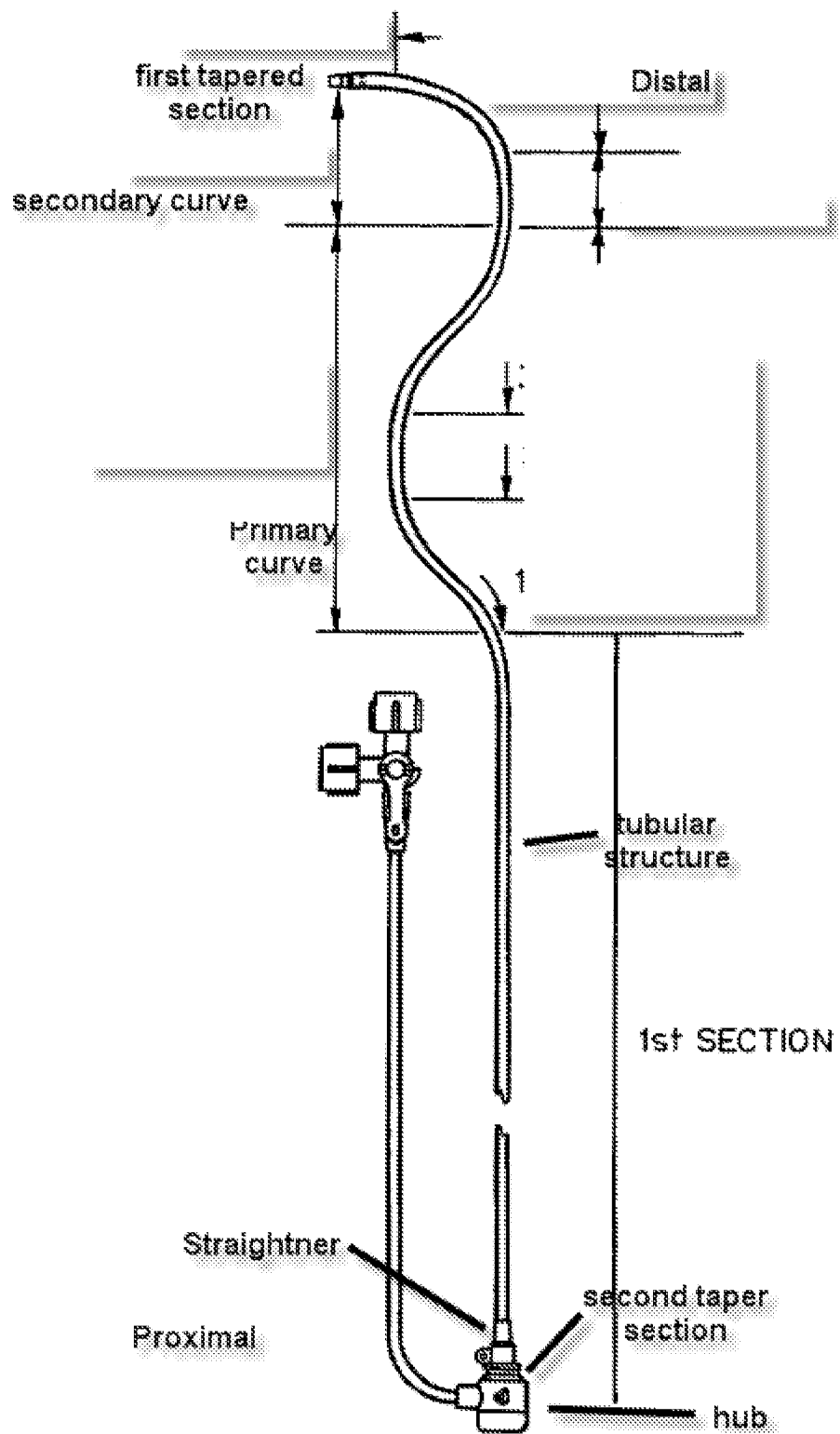
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20, 28-30, 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Swartz et al. (U.S. Patent Number 5,800,413).

Swartz discloses a guiding introducer. Swartz discloses a catheter (as in figure 2b for example) with a tubular structure, defining a single lumen, a primary curve (see marked figure below), a tapered section distal to the primary curve (see marked figure below), a secondary curve distal to the primary curve, wherein the first tapered section

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generally coincides in location with the secondary curve, and a straightener (see figure below).



Constructing the catheter from a polyurethane/polyether block amid copolymer (claim 2,17), with a steel braided material (claims 13-14), a tungsten radiopaque marker (15-16) and hydrophilic coating (18).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2, 13-17, 23, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz in view of Parker (U.S. Patent 5,221,270). Swartz discloses the claimed invention except for explicitly stating constructing the catheter from a polyurethane/polyether block amid copolymer, with a steel braided material, a tungsten radiopaque marker (15-16) and hydrophilic coating (18).

Parker teaches that it is known to constructing the catheter from a polyurethane/polyether block amid copolymer, with a steel braided material, a tungsten radiopaque marker as set forth in paragraphs at columns 2-4 to provide constructing a biocompatible, torqueable catheter that can has increased radiopacity for fluoroscopy or

imaging. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Swartz with constructing the catheter from a polyurethane/polyether block amid copolymer, with a steel braided material, and a tungsten radiopaque marker as taught by Parker, since such a modification would provide the system with for providing a biocompatible, torqueable catheter that can has increased radiopacity for fluoroscopy or imaging.

Claims 3-12, 21-22, 24-25, 27, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al.

Concerning claims 3, 4, 5, 6, 7, 8, 9, 24-25; Swartz discloses the claimed invention except for disclosing the exact size specifications of certain centimeter lengths of the catheter between the curves and tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to size the catheter with the exact dimensions of length of tapered catheter curve sections, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Although Swartz does not explicitly disclose these specific dimensions, they all fall within the range of normal catheter/micro catheters used in practice.

Concerning claim 10-12; Swartz discloses the claimed invention except for the primary curve is 360 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the 180 (as shown in figure 2C) degree curve to 360 degrees, since it has been held that where the general conditions

of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

Concerning claims 21-22, 24; Swartz discloses the claimed invention except for the specific hub length and dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a hub with the specific dimensions as in the claim limitations, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Concerning claim 27, 36-38; Swartz discloses the claimed invention except for the straightner, tapered end section, and second tapered section being formed separately removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the straightner, tapered end section, and second tapered section separately removable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin v. Erlichman*, 168 USPQ 177 (BdPatApp&Int 1969).

Concerning 31, Swartz discloses the claimed invention except for making the catheter out of a germ retarding material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the catheter formed from a germ retarding material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended



use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al. in view of Trotta

Swartz discloses the claimed invention except for constructing the tip in a hydrophilic coating. Trotta teaches that it is known to use the tip as a hydrophilic coating as set forth in paragraphs at columns 7-8 particularly column 7 line 53-68 to provide a low friction and highly viscous surface to aid in sliding. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Swartz with a hydrophilic coated tip as taught by Trotta, since such a modification would provide the system with a hydrophilic coated tip for providing a low friction and highly viscous surface to aid in sliding.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "**to the first curve**" in the 5<sup>th</sup> paragraph of the claim. There is insufficient antecedent basis for this limitation in the

claim. It is likely that the "first curve" is the "primary curve". Appropriate correction is required for consistent element terminology.

Claims 3, 8, 33, 34, 35, 36, 37, 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3, 8, 33, 34, 35, 36, 37, 38 recites the limitation "**the** second tapered section" in the beginning of each claim. There is insufficient antecedent basis for this limitation in the claim. It is recommended to change "the" to "a" each of the first introduction of the element in the claims.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "length of the second tapered section is variable" in claim 35 is a relative term which renders the claim indefinite. The term "Variable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Examiner is unable to ascertain the scope of this limitation. It appears from the specification and the drawings that the apparatus has a defined and fixed length. Appropriate correction is required.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where the "primary curve is 360 degrees" is not shown in the

drawings or described in the specification to understand how the first tapered portion relates to the 360 degree curve. Appropriate correction is required.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “primary curve is 360” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767